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A controlled study of intravenous immunoglobulin combined with prednisone in the treatment of IBM.

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Abstract

OBJECTIVE: To investigate whether the combination of intravenous immunoglobulin (IVIg) with prednisone improves muscle strength and alters endomysial inflammation in patients with sporadic inclusion body myositis (s-IBM).
BACKGROUND: In a previous controlled trial in s-IBM, IVIg did not significantly improve strength in spite of modest benefits in some muscle groups. The possibility that prednisone may have a synergistic effect with IVIg prompted another controlled trial. **METHODS:** Thirty-six patients with biopsy-proven IBM were randomized to receive IVIg or placebo monthly for 3 months. Before infusions, all patients were started on high-dose prednisone for 3 months. Primary outcome measures were differences in the 1) Quantitative Muscle Strength (QMT) testing; and 2) modified Medical Research Council (MRC) scores, between the patients randomized to IVIg + prednisone compared with those randomized to placebo + prednisone. Repeated open muscle biopsies were performed at random in 24 patients to determine changes in the number of autoinvasive T cells and necrotic muscle fibers. **RESULTS:** Nineteen patients were randomized to IVIg + prednisone and 17 to placebo + prednisone. No significant change was noted in muscle strength, assessed by QMT and MRC, from baseline to the 2nd, 3rd, or 4th month after treatment between the two groups. The number of necrotic fibers was reduced in the IVIg randomized group ($p < 0.01$), and the mean number of CD2+ cells was significantly decreased in both groups ($p < 0.0001$), denoting a steroid effect. **CONCLUSION:** IVIg combined with prednisone for a 3-month period was not effective in IBM. Endomysial inflammation was significantly reduced after treatment, but the reduction was not of clinical significance.

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